

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

MEDISIM LTD.,

Plaintiff,

- against -

BESTMED LLC,

Defendant.

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OPINION AND ORDER

10 Civ. 2463 (SAS)

X

SHIRA A. SCHEINDLIN, U.S.D.J.:

I. INTRODUCTION

Medisim Ltd. (“Medisim”) has brought this action against BestMed LLC (“BestMed”) for patent and copyright infringement, unfair competition, false designation of origin, false advertising, deceptive acts and practices, unfair competition, unjust enrichment, and an accounting.

Claim construction – the process wherein the court determines, as a matter of law, the meaning of disputed claim terms – is a task preferably tackled early on in a patent infringement action. A Markman hearing – which provides the parties the opportunity to argue for, and introduce evidence in support of, their proposed constructions – was held on April 28, 2011. The parties dispute the

meaning of nine terms and phrases appearing throughout U.S. Patent No. 7,597,668 (“the ‘668 Patent”). For ease of reference, a list of the constructions I have adopted is included at the conclusion of this Opinion.

II. BACKGROUND

A. The Invention

The measurement of body temperature is useful for assessing the health of a person.¹ In the past, invasive thermometers, those inserted into a body cavity, have been used. These invasive thermometers have several disadvantages. For example, they take a long time to obtain a reading and can cause discomfort to and require cooperation from the subject.² Non-invasive thermometers, on the other hand, cause less discomfort, but a large statistical deviation may exist between the temperature at an external measurement site and the core body temperature.³

The claimed invention relates to a non-invasive thermometer, which is designed to be placed against a patient’s skin to calculate core body

¹ See ‘668 Patent, Ex. A to Plaintiff Medisim’s Opening Claim Construction Brief (“Medisim Br.”), at col. 1 ll. 12-13.

² See *id.* col. 1 ll. 28-33.

³ See *id.* col. 1 ll. 23-38.

temperature.⁴ The thermometer has a probe with temperature sensors, which provide temperature readings from different thermal distances from the body's surface.⁵ These temperature readings use a heat flux calculation to compute a "deep tissue temperature" or "local temperature."⁶ The thermometer then uses the deep tissue temperature and an empirically-derived formula to calculate a "core body temperature."⁷

On October 6, 2009, the Patent and Trademark Office ("PTO") issued the '668 Patent – entitled Non-Invasive Temperature Measurement – to Moshe Yarden and named Medisim as the sole assignee.⁸ The '668 Patent incorporates an earlier patent, U.S. Patent No. 6,280,397 ("the '397 Patent") on which Yarden is named as a co-inventor and is also assigned to Medisim.

B. Procedural History

In November of 2004, BestMed and Medisim entered into a distributor contract where BestMed would be the sole distributor for Medisim in the United States and Canada for certain products to be developed by Medisim,

⁴ See *id.* col. 1 ll. 57-60.

⁵ See *id.* col. 1 ll. 61-63.

⁶ *Id.* col. 1 l. 65-col. 2 l. 2.

⁷ *Id.* col. 2 ll. 8-12.

⁸ See Medisim Br. at 1.

including the thermometer at issue in this litigation.⁹ Medisim alleges that during the time the parties were operating under the distributor agreement, BestMed began discussions with a company called K-Jump Health Co., LTD (“K-Jump”) to replace Medisim’s thermometer.¹⁰ Medisim also alleges that in 2009, BestMed terminated the distributor agreement with Medisim and began purchasing thermometers from K-Jump to sell in the United States.¹¹ BestMed denies both these allegations.¹² Medisim claims that the thermometer now sold by BestMed practices some or all of the claims of the ‘668 Patent and is not licensed or authorized by Medisim.¹³

Medisim asserts that BestMed has infringed directly and/or indirectly one or more claims of the ‘668 Patent, has infringed Medisim’s copyright, has committed acts of false designation of origin and unfair competition, has used false and misleading claims in advertising, has committed deceptive acts and practices, has committed acts of unfair competition, and has been unjustly

⁹ See Complaint (“Compl.”) ¶ 9.

¹⁰ See *id.* ¶ 11.

¹¹ See *id.* ¶ 13.

¹² See BestMed Answer, Affirmative Defenses, Counterclaims and Jury Demand (“Answer”) ¶ 11.

¹³ See Compl. ¶ 14.

enriched in violation of New York common law. Medisim is also requesting that this Court order BestMed to render an accounting and disgorgement of all profits as well as award Medisim punitive damages and attorneys' fees and a permanent injunction.¹⁴

C. Claim Language

Medisim alleges that BestMed is infringing on claims 1, 8, 15, 19, 21, 27, 32, and 35-37.¹⁵ Claims 1 and 21 are independent claims and are respectively directed to a thermometric device (apparatus claim) and a method for thermometric measurement (method claim).¹⁶ They share many of the same phrases. Claims 1 and 21 contains the following language. The disputed terms are emphasized.

Claim 1 A thermometric device, comprising:

a probe, comprising: a membrane configured to be applied to an external surface of a body of a subject; and one or more temperature sensors located within the probe in thermal contact with the membrane; and

a processing unit configured to receive a plurality of temperature readings from the one or more temperature sensors, to determine time-

¹⁴ See id. ¶¶ 24-71. In its answer, BestMed raises various counterclaims including declaratory judgement for patent non-infringement, declaratory judgement for patent invalidity and false patent marking. See generally Answer.

¹⁵ See Medisim Br. at 7.

¹⁶ See id.

dependent parameters of temperature change responsively to the plurality of temperature readings to *calculate, a deep tissue temperature* of the body at a location under the skin that is a source of heat conducted to the one or more temperature sensors, and to *calculate a core body temperature* by correcting for a difference between the core body temperature and the deep tissue temperature.

Claim 21 A method for thermometric measurement, comprising:

applying a *probe*, which comprises a heat-conducting *membrane* and *one or more temperature sensors* in thermal communication with the membrane, to an external surface of a body of a subject;

receiving a plurality of temperature readings from the one or more temperature sensors while the probe is applied to the surface of the body;

determining time-dependent parameters of temperature change responsively to the plurality of temperature readings;

calculating a deep tissue temperature of the body at a location under the skin that is a source of heat conducted to the one or more temperature sensors; and

calculating a core body temperature by correcting for a difference between the core body temperature and the deep tissue temperature.

With regard to the apparatus claims - claims 1, 8, 15, 19 and 36 - the parties seek construction of: "probe"; "membrane"; "one or more temperature sensors"; "configured to receive a plurality of temperature readings from the one or more temperature sensors"; "time-dependent parameters of temperature change"; "calculate"; "deep tissue temperature"; "to calculate a deep tissue temperature of the body at a location under the skin that is a source of heat"; "core

body temperature” and “to calculate a core body temperature.”¹⁷ With regard to the asserted method claims - claims 21, 27, 32, 35, and 37- the parties seek construction of the aforementioned phrases, as well as interpretation of which actor performs the claimed steps of “receiving a plurality of temperature readings”; “determining time-dependent parameters of temperature change”; “calculating a deep tissue temperature”; and “calculating a core body temperature by correcting for a difference between the core body temperature and the deep tissue temperature.”¹⁸

III. APPLICABLE LAW

Analysis of patent infringement involves two steps: (1) construction of the terms of the asserted claims and (2) a determination of whether the accused device infringes the claims, as construed.¹⁹ Claim construction is a question of law,²⁰ the purpose of which is to determine what is covered by an asserted claim. In other words, “[t]he construction of claims is simply a way of elaborating the

¹⁷ See Opening Claim Construction Brief by Defendant, BestMed, LLC (“BestMed Br.”) at 4.

¹⁸ See *id.*

¹⁹ See *Metabolite Labs., Inc. v. Laboratory Corp. of Am. Holdings*, 370 F.3d 1354, 1360 (Fed. Cir. 2004).

²⁰ See *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 384, 390-91 (1996).

normally terse claim language in order to understand and explain, but not to change, the scope of the claims.”²¹

The following canons of construction are often employed by courts in interpreting patent claims. However, the Federal Circuit has “recognized that there is no magic formula or catechism for conducting claim construction,”²² and it is apparent from experience that the various canons of claim construction will sometimes, if not often, lead to contradictory results. Accordingly, while these interpretive tools can be indispensable aids to a federal district court tasked with construing the meaning of a patent claim, the court must ultimately be guided by the core inquiry of claim construction: How a “person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application,” would understand the terms of the claim.²³

A. Intrinsic Evidence

Claims are to be construed in light of the intrinsic record, which “is the most significant source of legally operative meaning of disputed claim

²¹ *DeMarini Sports, Inc. v. Worth, Inc.*, 239 F.3d 1314, 1322 (Fed. Cir. 2001) (quoting *Embrex, Inc. v. Services Eng’g Corp.*, 216 F.3d 1343, 1347 (Fed. Cir. 2000)).

²² *Phillips v. AWH Corp.*, 415 F.3d 1303, 1324 (Fed. Cir. 2005) (en banc).

²³ *Id.* at 1313.

language.”²⁴ The intrinsic record includes the claims themselves, the rest of the patent specification, and the prosecution history if in evidence.

1. Claim Language

Judicial interpretation must begin with and remain focused upon the “words of the claims themselves . . . to define the scope of the patented invention.”²⁵ On occasion, “the ordinary meaning of claim language as understood by a person of skill in the art” will be sufficiently apparent that the claim language itself is all that is needed to construe the claims at issue.²⁶ However, even when the terms in a claim are not self-explanatory, “[t]he context in which a term is used in the asserted claim can be highly instructive. To take a simple example, [the use of the term] ‘steel baffles’ . . . strongly implies that the term ‘baffles’ does not inherently mean objects made of steel.”²⁷

2. The Specification

Apart from the claims themselves, a patent consists of a written description of the patented invention. This written description, which is also

²⁴ *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

²⁵ *Id.*

²⁶ *Phillips*, 415 F.3d at 1314 (citation omitted).

²⁷ *Id.*

referred to as the specification,²⁸ typically includes: an abstract of the invention; a description of the invention's background; a summary of the invention; patent drawings; and a detailed description that discusses preferred embodiments of the invention. Because the specification must, by statute, enable one skilled in the art to practice the invention,²⁹ it "is always highly relevant to the claim construction analysis."³⁰ Accordingly, it is axiomatic that the "claims must be read in view of the specification, of which they are a part."³¹

However, there is a difference "between using the specification to

²⁸ The terminology used to describe the parts of a patent can be slightly confusing. Technically, the specification includes both the claims and the written description. However, courts typically use the term specification to refer to the written description on its own and as distinct from the claims. For purposes of consistency, I adopt this common usage.

²⁹ See 35 U.S.C. § 112 ("The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."). The Federal Circuit has also explained that courts should rely on intrinsic evidence because a person of ordinary skill in the field would use "the patent specification and the prosecution history" to understand the invention claimed by the patent. *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998). *Accord Phillips*, 415 F.3d at 1311-14.

³⁰ *Phillips*, 415 F.3d at 1315 (quotation marks and citations omitted).

³¹ *Id.* In fact, a claim interpretation that excludes a preferred embodiment described in the specification is "rarely, if ever, correct." *Vitronics*, 90 F.3d at 1583.

interpret the meaning of a claim and importing limitations from the specification into the claim.”³² The former is permissible; the latter is not. Although it is often difficult to distinguish between these interpretive outcomes, the Federal Circuit has provided some general guidance to aid district courts. Because it is the claims themselves that “define the scope of the right to exclude,”³³ the specification should normally only be used to limit a claim: (1) if the claim “explicitly recite[s] a term in need of definition”³⁴; or (2) if the specification unambiguously defines a term, *i.e.*, if “a patent applicant has elected to be a lexicographer by providing an explicit definition in the specification for a claim term.”³⁵ While these guideposts do not make every question an easy one,³⁶ they do provide an informed starting point from which to begin interpretation.

3. Prosecution History

The prosecution history of a patent, which is part of the “intrinsic

³² *Phillips*, 415 F.3d at 1323.

³³ *Renishaw PLC v. Marposs Societa' Per Azioni*, 158 F.3d 1243, 1248 (Fed. Cir. 1998).

³⁴ *Id.*

³⁵ *Id.* at 1249.

³⁶ See *Phillips*, 415 F.3d at 1323 (“In the end, there will still remain some cases in which it will be hard to determine whether a person of skill in the art would understand the embodiments to define the outer limits of the claim term or merely to be exemplary in nature.”).

evidence,” “consists of the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent.”³⁷ “Because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes.”³⁸ Nonetheless, “[l]ike the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent,” and accordingly, “can often inform the meaning of the claim language[.]”³⁹

B. Extrinsic Evidence

The extrinsic record “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.”⁴⁰ Because extrinsic evidence (unlike intrinsic evidence) is not part of “the indisputable public record,” putting too much weight on that evidence “poses the risk [of] . . . undermining the public notice functions of patents.”⁴¹

³⁷ *Id.* at 1317(citation omitted).

³⁸ *Id.* (citations omitted).

³⁹ *Id.* (citations omitted).

⁴⁰ *Id.* (citations omitted).

⁴¹ *Id.* at 1319.

Nevertheless, while extrinsic evidence is less important than intrinsic evidence, it remains useful and district courts are “authorized . . . to rely upon [it].”⁴²

“Within the class of extrinsic evidence, the court has observed that dictionaries and treatises can be useful in claim construction.”⁴³ However, “[g]eneral dictionaries . . . strive to collect all uses of particular words Thus, the use of the dictionary may extend patent protection beyond what should properly be afforded by the inventor’s patent.”⁴⁴ “Moreover, different dictionaries may contain somewhat different sets of definitions for the same words.”⁴⁵ “A claim should not rise or fall based upon the preferences of a particular dictionary editor, or the court’s independent decision, uninformed by the specification, to rely on one dictionary rather than another.”⁴⁶ Finally, “authors of dictionaries . . . may simplify ideas . . . and may thus choose a meaning that is not pertinent to the understanding of particular claim language.”⁴⁷ Nonetheless, “[d]ictionaries or comparable sources are often useful to assist in understanding the commonly

⁴² *Id.* at 1317.

⁴³ *Id.* at 1318 (citations omitted).

⁴⁴ *Id.* at 1322 (citations omitted).

⁴⁵ *Id.* (citations omitted).

⁴⁶ *Id.* (citations omitted).

⁴⁷ *Id.* (citations omitted).

understood meaning of words and have been used both by our court and the Supreme Court in claim interpretation.”⁴⁸

C. Enablement Requirement

“Whether a claim satisfies the enablement requirement of 35 U.S.C. § 112, ¶ 1 is a question of law.”⁴⁹ The “enablement requirement” is satisfied when one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation.”⁵⁰ To avoid invalidity, “[t]he scope of the claimed invention must be enabled.”⁵¹ To be enabled, “[t]he scope of the claims must be less than or equal to the scope of the enablement to ensure that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims.”⁵²

However, “the maxim that claims should be construed to preserve their validity” has been limited to “cases in which the court concludes, after applying all the available tools of claim construction, that the claim is still

⁴⁸ *Id.*

⁴⁹ *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008).

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *Id.*

ambiguous.”⁵³

D. Means-Plus-Function

Title 35 U.S.C. § 112, ¶ 6 states:

An element in a claim for combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

Means-plus-function claiming applies to “purely functional limitations that do not provide the structure that performs the recited function.”⁵⁴ It “represents a quid pro quo by permitting inventors to use a generic means expression for a claim limitation provided that the specification indicates what structure(s) constitute(s) the means.”⁵⁵ Courts “have made clear that the use of the term ‘means’ is central to the analysis.”⁵⁶ The use of the word “means” in a patent creates a presumption

⁵³ *Phillips*, 415 F.3d at 1327.

⁵⁴ *Id.* at 1311 (citing *Watts v. XL Sys., Inc.*, 232 F.3d 877, 880-81 (Fed. Cir. 2000)).

⁵⁵ *Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374, 1382 (Fed. Cir. 1999) (citing *O.I. Corp. v. Tekmar Corp.*, 115 F.3d 1576, 1583 (Fed. Cir. 1997)).

⁵⁶ *Personalized Media Commc'n's, LLC v. International Trade Comm'n*, 161 F.3d 696, 703 (Fed. Cir. 1998).

that 35 U.S.C. §112, ¶ 6 applies. “Once the court has concluded the claim limitation is a means-plus-function limitation, the court must first identify the function of the limitation. The court next ascertains the corresponding structure in the written description that is necessary to perform that function.”⁵⁷

“When a claim term lacks the word ‘means,’ the presumption can be overcome if the challenger demonstrates that ‘the claim term fails to ‘recite sufficiently definite structure’ or else recites ‘function without reciting sufficient structure for performing that function.’”⁵⁸ “Thus, the presumption flowing from the absence of the term ‘means’ is a strong one that is not readily overcome.”⁵⁹ Courts have seldom held “that a limitation not using the term ‘means’ must be considered to be in means-plus-function form” and ‘the circumstances must be

⁵⁷ *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1375 (Fed. Cir. 2003) (citing *Micro Chem., Inc. v. Great Plains Chem. Co.*, 194 F.3d 1250, 1258 (Fed. Cir. 1999)).

⁵⁸ *Inventio AG v. ThyssenKrupp Elevator Americas Corp.*, – F.3d –, No. 2010-1525, 2011 WL 2342744, at *5 (Fed. Cir. June 15, 2011) (quoting *CCS Fitness v. Brunswick Corp.*, 288 F.3d 1359, 1369 (Fed. Cir. 2001) (quoting *Watts*, 232 F.3d at 880)).

⁵⁹ *Id* (citing *Lighting World, Inc. v. Birchwood Lighting, Inc.*, 382 F.3d 1354, 1358 (Fed. Cir. 2004)).

[unusual] to overcome the presumption.”⁶⁰

IV. DISCUSSION

A. A Thermometric Device, Comprising: A Probe, Comprising a Membrane Configured to be Applied to an External Surface of a Body of a Subject; and One or More Temperature Sensors Located Within the Probe in Thermal Contact with the Membrane

1. “Probe”

Medisim requests that I construe the term “probe” to mean a “[p]ortion of thermometer including one or more temperature sensors.”⁶¹ BestMed proposes that “probe” should mean a “non-invasive portion of thermometer adapted for contacting the skin of the subject.”⁶² BestMed argues that including “sensors” would make the definition redundant with respect to the rest of the claim.⁶³ Medisim contends that including “sensors” is important because without it the definition would limit the probe to the portion of the thermometer that

⁶⁰ *Massachusetts Institute of Tech. v. Abacus Software*, 462 F.3d 1344, 1356 (Fed. Cir. 2008) (quoting *Lighting World*, 382 F.3d at 1362) (alteration in original).

⁶¹ Medisim Br. at 7.

⁶² BestMed Br. at 5.

⁶³ See *id.* at 6.

actually touches the skin.⁶⁴ Medisim's definition makes clear that the probe "compris[es] . . . one or more temperature sensors." However, taking Medisim's argument to its logical conclusion, the definition should also include "membrane." Claim 1 clearly states that the probe "compris[es] . . . a membrane . . . and . . . one or more temperature sensors."⁶⁵ Therefore, I will define "probe" to mean "portion of thermometer including a membrane and one or more temperature sensors that touches the exterior skin."

2. Membrane

Medisim defines membrane as "heat conducting part with relatively high thermal conductivity"⁶⁶ while BestMed proposes the definition "a thin pliable layer or sheet of material."⁶⁷ Looking first to the claim language, Medisim's definition is unworkable for two reasons. *First*, as BestMed argues, the word

⁶⁴ See 4/28/11 Transcript of Markman Hearing ("4/28/11 Tr.") at 25: 6-8. *Accord* Plaintiff's Brief in Opposition to Defendant's Proposed Construction of Claim Terms ("Medisim Op. Br.") at 3.

⁶⁵ Medisim concedes that "probe" should include "membrane." See 4/28/11 Tr. at 29: 7-8.

⁶⁶ *Id.* at 41: 7-9.

⁶⁷ BestMed Br. at 7.

“part” is too broad.⁶⁸ Medisim could have claimed “heat conducting [part]” but it chose the word “membrane,” which implies a particular type of physical structure. According to BestMed, the Court should not fix this ill-conceived claim.⁶⁹ I find it significant that the patent uses the word “membrane” and therefore decline to substitute the word “material” for “membrane.” *Second*, Medisim’s addition of the phrases “heat conducting” and “with relatively high thermal conductivity” to modify “material” does not help. Claim 21 recites “a heat-conducting membrane.” The addition of the word “heat-conducting” implies that heat and thermal conductivity is not included in the definition of “membrane.”⁷⁰

As with the claim language, the specifications do not help define “membrane.” Rather than defining “membrane,” the specifications merely describe the membrane’s function. For example, the specifications provide that

⁶⁸ See Responsive Claim Construction Brief by Defendant, BestMed, LLC (“BestMed. Resp.”) at 4.

⁶⁹ See *id.* (citing *Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1425 (Fed Cir. 1997) (“[A]s between the patentee who had a clear opportunity to negotiate broader claims but did not do so . . . it is the patentee who must bear the cost of its failure to seek protection for this foreseeable alteration of its claimed structure.”)).

⁷⁰ See, e.g., *Phillips*, 415 F.3d at 1314 (citation omitted) (“[T]he claim in this case refers to ‘steel baffles,’ which strongly implies that the term ‘baffles’ does not inherently mean objects made of steel.”).

the membrane is “heat-conducting”⁷¹ and “configured to be applied to an external surface of a body of a subject.”⁷² When the membrane is concave, it “conforms to slight protrusions or bumps on the body surface.”⁷³ When the membrane is convex, it “pushes into the skin.”⁷⁴ Other than stating that the membrane “has a diameter of 5-25 mm,”⁷⁵ the specifications shed no light as to what the membrane is. In such circumstances, it is appropriate to look to dictionary definitions of the term.⁷⁶ The 2002 version of *Webster’s Third New International Dictionary* defines “membrane” as “a thin soft pliable sheet or layer especially of animal or vegetable origin.”⁷⁷ This dictionary definition of “membrane” was current in 2009, the year the ‘668 patent was filed. Taking this definition as a starting point, I find that the phrase “especially of animal or vegetable origin” is obviously inapplicable to the

⁷¹ ‘668 Patent col. 1 ll. 58-59.

⁷² *Id.* col. 2 ll. 34-35.

⁷³ *Id.* col. 5 ll. 7-10.

⁷⁴ *Id.* col. 5 ll. 10-11.

⁷⁵ *Id.* col. 5 ll. 4-5.

⁷⁶ See *Phillips*, 415 F.3d at 1322 (“Dictionaries or comparable sources are often useful to assist in understanding the commonly understood meaning of words and have been used both by our court and the Supreme Court in claim interpretation.”) (citations omitted).

⁷⁷ *Webster’s New Universal Unabridged Dictionary* (3rd ed. 2002).

claimed term. Also, the words “thin” and “pliable” are not found anywhere in the patent. Therefore, I will not read “thin” and “pliable” into the definition of “membrane.” For these reasons, I will construe “membrane” to mean “a layer or sheet of material.”

3. “One or More Temperature Sensors”

The phrase “one or more temperature sensors” is repeated throughout the asserted claims. Medisim construes the phrase “one or more temperature sensors” as “one or more thermistor or resistance temperature defectors (RTDs), or any form of thermistor, temperature sensor, or thermocouple.”⁷⁸ BestMed proposes the definition “at least two temperature sensors for determining heat flux therebetween.”⁷⁹

The crucial difference between the parties’ constructions pertains to the required number of temperature sensors. Medisim points to the plain language of the claim term and argues that “one or more” means just that: the device may have as few as one temperature sensor.⁸⁰ BestMed believes the phrase should be defined as “at least two temperature sensors” because heat flux requires at least

⁷⁸ Medisim Br. at 9.

⁷⁹ BestMed Br. at 8.

⁸⁰ See Medisim Br. at 9.

two sensors and the patent does not teach how the thermometer would work with only one sensor.⁸¹ BestMed argues that construing the phrase according to its plain meaning would result in a non-enabled, invalid claim under 35 U.S.C. § 112, ¶ 1.⁸²

Before I determine whether a particular construction would render the phrase invalid, I must first find the phrase to be ambiguous.⁸³ As to the minimum number of temperature sensors, the plain language of the “one or more” does not leave room for interpretation. Because the claimed phrase is unambiguous, I will construe the claimed term without considering whether the construction would render the phrase invalid.⁸⁴

I therefore define “one or more temperature sensors” to mean “one or

⁸¹ See BestMed Br. at 8-9.

⁸² See *id.* at 9.

⁸³ See *Phillips*, 415 F.3d at 1327 (“While we have acknowledged the maxim that claims should be construed to preserve their validity, we have not applied that broadly Instead, we have limited the maxim to cases in which the court concludes, after applying all the available tools of claim construction, that the claim is still ambiguous.”).

⁸⁴ *Id.* (“[T]he claimed term at issue is not ambiguous. Thus it can be construed without need to consider whether one possible construction would render the claim invalid while the other would not. The doctrine of construing claims to preserve their validity, a doctrine of limited utility in any event, therefore has no applicability here.”).

more thermistor or resistance temperature defectors (RTDs), or any form of thermistor, temperature sensor, or thermocouple.”⁸⁵

B. A Processing Unit Configured to Receive a Plurality of Temperature Readings from the One or More Temperature Sensors, To Determine Time-dependent Parameters of Temperature Change Responsively to the Plurality of Temperature Readings, to Calculate, a Deep Tissue Temperature of the Body at a Location Under the Skin that Is a Source of Heat Conducted to the One or More Temperature Sensors, and to Calculate a Core Body Temperature by Correcting for a Difference Between the Core Body Temperature and the Deep Tissue Temperature

1. “Configured to Receive a Plurality of Temperature Readings from the One or More Temperature Sensors”

Medisim proposes the definition “[processing unit] configured to receive temperature readings from one or more temperature sensors.”⁸⁶ BestMed proposes the definition “[processing unit]⁸⁷ configured⁸⁸ to receive multiple

⁸⁵ Other than objecting to the minimum number of temperature sensors, BestMed does not contest the remainder of Medisim’s proposed definition.

⁸⁶ Medisim Br. at 11.

⁸⁷ At the Markman Hearing, the parties agreed on “processing unit.” See 4/28/11 Tr. at 71: 24-25.

⁸⁸ At the Markman Hearing, BestMed agreed to “configured.” See *id.* at 74: 25 - 75: 1.

external body surface temperature reading inputs from the at least two sensors.”⁸⁹

There are two main differences between the proposed definitions. The first relates to the number of sensors. The second relates to the site from which the temperature readings are obtained. As discussed above, the patent provides for “one or more sensors.” As to where the temperature readings are obtained, both parties agree that inputs may be taken from places other than the body surface.⁹⁰ However, Medisim believes that only one of the plurality of temperature readings must be taken from the body’s surface.⁹¹ BestMed believes that at least two of the readings must be taken from the body’s surface.⁹²

Claim 1 states that when the thermometer is placed on the skin, the “processing unit” receives “a plurality of temperature readings” from “one or more

⁸⁹ BestMed Br. at 14.

⁹⁰ See BestMed Resp. at 8. Medisim claims its definition is superior because the probe can be preheated and ambient air temperature can also affect the sensor readings. This, Medisim believes, establishes that the sources of heat are not limited to the body’s surface. See Medisim Op. Br. at 9. However, BestMed claims that it agrees that inputs can come from sources other than the body’s surface. BestMed’s argument is that more than one temperature must come from the body’s surface. See 4/28/11 Tr. at 73: 2-8.

⁹¹ See Medisim Op. Br. at 9.

⁹² See 4/28/11 Tr. at 72: 20-21.

temperature sensors.”⁹³ To calculate “deep tissue temperature,” the “temperature sensors” measure “a source of heat” found under the skin.⁹⁴ BestMed points to these two statements and argues that claim 1 “specifies that the source of heat for the sensors is found under the skin”⁹⁵ and “[l]ogically, the multiple temperature readings received by the processing unit must be from the subject’s skin.”⁹⁶ The claim language does not support BestMed’s conclusion. Claim 1 does not require that the deep tissue temperature be the only source of heat conducted to the temperature sensor(s). Deep tissue temperature is only “*a* source of heat conducted to the one or more temperature sensors.”⁹⁷ The claim only requires that one of the sources of heat for the temperature sensors come from the skin. Furthermore, as Medisim points out, in one of the embodiments, a printed circuit board (“PCB”) can comprise heating elements and can affect the input to the one or more temperature sensors.⁹⁸

⁹³ ‘668 Patent col. 10 ll. 9-11.

⁹⁴ *Id.* col. 10 ll. 13-15.

⁹⁵ BestMed Br. at 15.

⁹⁶ *Id.*

⁹⁷ ‘668 Patent col. 10 ll. 14-15 (emphasis added).

⁹⁸ See *id.* col. 6 ll. 43-45.

Although I reject BestMed's definition, I find that Medisim's definition fails to reflect that fact that at least one of the temperature inputs must be derived from the body's surface. Accordingly, I will construe the phrase to mean "[processing unit] configured to receive temperature readings, at least one of which comes from the external body surface, from one or more temperature sensors."

2. "To Determine Time-Dependent Parameters of Temperature Change Responsively to the Plurality of Temperature Readings"

For the phrase "time-dependent parameters of temperature change," Medisim proposes the definition, "values of temperature change that vary with time."⁹⁹ The values, Medisim claims, may be numbers that are based on straight temperature changes – *i.e.*, temperature change itself.¹⁰⁰ BestMed proposes the definition: "multiple temperature rate of change values with respect to time that are taken at different times."¹⁰¹

The main dispute between the parties is whether "time-dependent

⁹⁹ See 4/28/11 Tr. at 76: 16-17.

¹⁰⁰ See *id.*

¹⁰¹ BestMed Br. at 16. At the Markman hearing, BestMed agreed to replace the word "series" with "multiples that are taken at different times." See 4/28/11 Tr. at 85: 18-20. Medisim agrees that there are multiple temperature readings taken at different times. See *id.*

parameters of temperature change” consists only of temperature rates of change or if it also encompasses other values. BestMed believes that “time-dependent parameters of temperature change” only includes rates of temperature change.¹⁰² If the parameters are “time-dependent,” BestMed argues, the parameters must be temperature changes that depend on time – *i.e.*, a rate of change.¹⁰³ Medisim’s construction includes rates of temperature change as well as values such as straight temperature difference.¹⁰⁴ In support of this definition, Medisim points to the only core body temperature formula expressed in the ‘668 Patent. The formula includes the variable $T_{b10 - 2}$, which is expressed in degrees and is defined as “the difference between the reading of the first sensor after 10 intervals and the first reading of the first sensor after two intervals.”¹⁰⁵ Although $T_{b10 - 2}$ is expressed in degrees and does not have a time component in its dimensions, Medisim believes it still qualifies as “time-dependent” because its value depends on the passage of time.¹⁰⁶ Therefore, Medisim reasons that “time-dependent parameters of temperature change” encompasses straight temperature difference as well as rates

¹⁰² See 4/28/11 Tr. at 82: 13-14.

¹⁰³ See *id.* at 89: 16-19.

¹⁰⁴ See *id.* at 80: 22-23.

¹⁰⁵ See ‘668 Patent col. 9 ll. 53-54.

¹⁰⁶ See 4/28/11 Tr. at 79: 19-80: 20.

of temperature change.

BestMed also directs the Court's attention to $T_{b10 - 2}$. BestMed argues that $T_{b10 - 2}$ would be included in BestMed's definition as well because a "rate of change" is merely a change in temperature over some period of time.¹⁰⁷ Medisim disagrees because variables such as $T_{b10 - 2}$ are expressed in degrees.¹⁰⁸

I agree with Medisim. "Rate of change" has a common ordinary meaning that includes a quantity of something measured per unit of something else. BestMed's interpretation of "rate of change" goes against this ordinary meaning. It is illogical to interpret a variable such as $T_{b10 - 2}$, with no time component in its dimensions, as a "rate of change."

At the Markman hearing, the parties agreed that there are multiple parameters determined at different times.¹⁰⁹ Taking this into account, I will construe "time-dependent parameters of temperature change" to mean "multiple values of temperature change that vary with time and that are taken at different times."

3. To Calculate, a Deep Tissue Temperature of the Body at a Location Under the Skin That Is a Source of Heat

¹⁰⁷ See *id.* at 86: 15-16.

¹⁰⁸ See *id.* at 88: 24-25.

¹⁰⁹ See *id.* at 85: 11-25.

Conducted to the One or More Temperature Sensors

Medisim proposes to separately construe “to calculate” and “a deep tissue temperature.” BestMed wishes to define the phrase “to calculate a deep tissue temperature of the body at a location under the skin that is a source of heat” found in the apparatus claims and the phrase “calculating a deep tissue temperature of the body at a location under the skin that is a source of heat” found in the method claims in their entirety.

a. “To Calculate”

Medisim wishes to construe “to calculate” as “[u]se of mathematical procedure to compute, estimate, approximate, predict or determine.” BestMed proposes the definition “to ascertain/ascertaining by computation.” The dispute boils down to whether “to calculate” should include mere prediction and estimation.

I will define “to calculate” as “using a computation to estimate, approximate, predict or determine.” At the Markman hearing, the parties agreed to this definition.¹¹⁰

b. “Deep Tissue Temperature”

At the Markman hearing, the parties agreed that this term need not be

¹¹⁰ See *id.* at 97: 16-21.

construed.¹¹¹

c. BestMed's Definition

BestMed argues that the entire phrase “to calculate/[calculating] a deep tissue temperature of the body at a location under the skin that is a source of heat” should be interpreted under 35 U.S.C. §112, ¶ 6 as a means-plus-function claim limitation.¹¹² Although the patent does not use the word “means,” BestMed believes that §112, ¶ 6 treatment is appropriate because “the only structure recited [in claims 1 and 21] is a generic ‘processing unit,’¹¹³ which by itself does not connote a sufficient structure.¹¹⁴ According to BestMed, because the phrase is subject to §112, ¶ 6 and the only algorithm for calculating deep tissue temperature disclosed in the patent is the one referenced in the ‘397 Patent, the phrase should be construed as limited to the ‘397 Patent algorithm.¹¹⁵

The phrase at issue is not a means-plus-function element under §112, ¶ 6. First, the phrase does not contain the word “means.” “[P]rocessing unit”

¹¹¹ See 4/28/11 Tr. at 108: 18-19.

¹¹² See BestMed Br. at 19.

¹¹³ *Id.* at 20.

¹¹⁴ See *id.*

¹¹⁵ *Id.* (citing *WMS Gaming, Inc. v. International Game Tech*, 184 F.3d 1339, 1348 (Fed. Cir. 1999)).

therefore presumptively connotes a sufficient structure to those of skill in the art.¹¹⁶ Furthermore, the surrounding claim language describes the function of the “processing unit.” For example, claim 1 recites that the “processing unit” is capable of “determin[ing] time-dependent parameters of temperature change,” of “calculat[ing] . . . deep tissue temperature” and of “correcting for the difference between the core body temperature and the deep tissue temperature.”¹¹⁷ In light of the strong presumption against applying § 112, ¶ 6 and this claim language, I find that “processing unit” connotes a sufficiently definite structure to a person of ordinary skill in the art to avoid § 112, ¶ 6 treatment.¹¹⁸

4. “To Calculate a Core Body Temperature by Correcting for a Difference Between the Core Body Temperature and the Deep Tissue Temperature”

a. Medisim’s Construction

¹¹⁶ See *Inventio AG*, 2011 WL 2342744, at * 9 (finding that “computing unit” and “modernizing device” presumptively connote sufficiently definite structure when the claimed phrase does not contain the word “means”) (citing *Personalized Media Commc’ns*, 161 F.3d at 703-04).

¹¹⁷ See ‘668 Patent col. 10 ll. 11-18.

¹¹⁸ See *Inventio AG*, 2011 WL 2342744, at * 10 (finding that without the word “means,” the defendant “had the burden to show that the ‘computing unit’ terms are so structurally devoid that [the court] should rewrite them in means-plus-function format. The claims and the written descriptions, however, indicate that those of skill in the art would understand a computing unit to connote sufficiently definite structure. Thus, on this record, [the defendant] has failed to meet its burden.”).

Medisim construes “to calculate” and “core body temperature” separately. As with the previous phrase, BestMed argues that the phrase should be defined as a single term.

i. “To Calculate”

For the reasons given above, I will define “to calculate” as “using a computation to estimate, approximate, predict or determine.”

ii. “Core Body Temperature”

For “core body temperature,” Medisim proposes the definition “the temperature that is an indication of a person’s health (if elevated, commonly referred to as a ‘fever’), and is commonly measured orally, rectally, and [axillarily].”¹¹⁹ BestMed offers the definition “the temperature of blood in the pulmonary artery.”¹²⁰

Medisim believes “peripheral temperatures” are “core body temperatures” because “core body temperature” can be measured at a variety of locations, including orally, rectally and axillarily.¹²¹ Medisim’s definition for

¹¹⁹ Medisim Br. at 17.

¹²⁰ BestMed Br. at 21.

¹²¹ See Medisim Op. Br. at 17. *Accord* 4/28/11 Tr. at 119: 11-19 (“[Core body temperature is] a temperature that’s taken at a body cavity, or it can be done internally, as well. But it’s the indicator of a person’s health.”).

“core body temperature” thus encompasses “peripheral temperature[s],” taken orally, rectally and axillary.¹²² I disagree. Although “core body temperature” can be approximated by measurements taken from a variety of places,¹²³ the plain language of the ‘668 Patent treats core body temperature and peripheral temperature as distinct terms. Looking to the specifications, the Background section of the ‘668 Patent states:

[A] body temperature is measured by a thermometer positioned in a body cavity, such as the mouth, the axilla, or the rectum. A core body temperature, commonly measured in the pulmonary artery, is generally considered a better indicator of a subject’s health than peripheral temperatures of the aforementioned body cavities.¹²⁴

The ‘668 Patent distinguishes these two temperatures based on (1) the location where they are measured and (2) how indicative they are of the subject’s health.¹²⁵ Furthermore, the ‘668 Patent points out that there is a “poor correlation between external and peripheral temperatures with the core body temperature.”¹²⁶ Medisim’s proposed definition of “core body temperature” does not account for

¹²² See 4/28/11 Tr. at 115: 2-7.

¹²³ After all, the purpose of the invention is to approximate core body temperature based on temperature measurements at the body surface. See ‘668 Patent col. 1 ll. 54-56.

¹²⁴ *Id.* col. 1 ll. 13-19.

¹²⁵ See *id.*

¹²⁶ *Id.* col. 1 ll. 39-40.

these distinctions and conflates the two temperatures.

For these reasons, “core body temperature” is defined as “the temperature of blood in the pulmonary artery.”¹²⁷

b. BestMed’s Construction

BestMed construes the entire phrase “to calculate a core body temperature” as “to calculate the temperature of blood in the pulmonary artery according to the algorithm set forth in the ‘668 Patent at col. 9, ll. 31-63.”¹²⁸ BestMed argues that, as with “deep tissue temperature,” the calculation of “core body temperature” is done by a “processing unit,” which BestMed argues should be construed as a “means” clause under §112, ¶6.¹²⁹

However, for the same reasons discussed above, I again conclude that the phrase is not a means-plus-function element under §112, ¶ 6.

C. Disagreement Over the Performer of Various Claimed Methods Steps

¹²⁷ The purpose of the invention is to determine a person’s core body temperature in a non-invasive but more accurate manner. *See id.* col. 1 ll. 36-38. It would defy common sense to then define “core body temperature” to include peripheral temperatures when, according to the ‘668 Patent itself, there is a “poor correlation” between peripheral temperatures and core body temperature and peripheral temperatures are not as indicative of the subject’s health as temperatures taken at the pulmonary artery. *See id.* col. 1 ll. 39-40.

¹²⁸ BestMed Br. at 22.

¹²⁹ *See id.* at 23.

The final dispute relates to *who* conducts some of the steps in the method claims. Here, claim 21 is the relevant independent claim. Unlike claim 1, claim 21 does not specify who is “applying a probe . . . to an external surface,” “receiving a plurality of temperature readings”; “determining time-dependent parameters of temperature change”; “calculating a deep tissue temperature” and “calculating a core body temperature.”¹³⁰ Both parties agree that the first step of “applying a probe” is performed by the user of the thermometer.¹³¹ However, there is disagreement as to who performs the remaining steps. BestMed argues that these remaining steps are performed by a “processing unit”¹³² whereas Medisim argues that the steps are performed by the user employing the thermometer.¹³³

I conclude that the first step is performed by the user of the thermometer but the remaining steps are performed by the processing unit.

V. CONCLUSION

For the aforementioned reasons I construe the disputed terms within claim 1 as follows:

¹³⁰ See ‘668 Patent col. 11 ll. 25-41.

¹³¹ See Medisim Br. at 19. See also BestMed Br. at 24.

¹³² See 4/28/11 Tr. at 143: 9.

¹³³ See Medisim Br. at 19.

“Probe” means “portion of thermometer including a membrane and one or more temperature sensors that touches the exterior skin.”

“Membrane” means “a layer or sheet of material.”

“One or more temperature sensors” means “one or more thermistor or resistance temperature defectors (RTDs), or any form of thermistor, temperature sensor, or thermocouple.”

“Configured to receive a plurality of temperature readings from the one or more temperature sensors” means “configured to receive temperature readings, at least one of which comes from the external body surface, from one or more temperature sensors.”

“Time-dependent parameters of temperature change,” means “multiple values of temperature change that vary with time and that are taken at different times.”

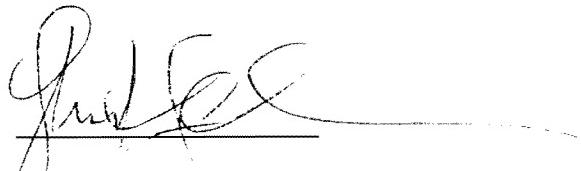
“To calculate” as “using a computation to estimate, approximate, predict or determine.”

“Core body temperature” as “the temperature of blood in the pulmonary artery.”

In claim 21, the user is “applying a probe . . . to an external surface,” while the processing unit is “receiving a plurality of temperature readings”;

“determining time-dependent parameters of temperature change”; “calculating a deep tissue temperature” and “calculating a core body temperature.”

SO ORDERED:



Shira A. Scheindlin
U.S.D.J.

Dated: New York, New York
July 7, 2011

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